

Notice of Allowability

Application No.

09/807,809

Examiner

Maria B. Marvich, PhD

Applicant(s)

POSSEE ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to RCE/amendment 10/30/07.
2. ☒ The allowed claim(s) is/are 27, 29, 31 and 33.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/07 has been entered.

Claims 27-34 are pending in this office action.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Elena S. Polovnikova, on January 22, 2008.

The application has been amended as follows:

IN THE CLAIMS:

Claims 28, 30, 32 and 34 have been cancelled.

27. (Previously Presented)

A method for cloning a gene comprising the steps of:

(i) providing a naked circular replication-deficient baculovirus vector capable of being maintained in a bacterial cell;

(ii) providing a rescue vector comprising[[,]] (a) a nucleic acid sequence, which is capable of restoring replication [[in]] to the replication-deficient baculovirus vector, and (b) at least one gene to be cloned; and

(iii) permitting the circular replication-deficient baculovirus vector and the rescue vector to recombine in an insect cell to produce a replication-enabled baculovirus vector comprising the at least one gene to be cloned; ~~and~~

~~(iv) growing the replication-enabled baculovirus vector within a suitable invertebrate cell.~~

Reasons for Allowance

The Declaration under 37 CFR 1.132 filed 10/30/2007 is sufficient to overcome the rejection of claims 27-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Campos et al (US 6,911,206; see entire document) as evidenced by Kool et al (PNAS, 1994, Vol. 91, pp. 11212-11216) and claim 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campos et al (US 6,911,206; see entire document) in view Merrington et al (Virology, 1996, pages 338-348~ see entire document). The sole issue remaining in the office action mailed 9/10/07 was whether the absence of teaching in Campos for ***digestion and linearization*** of the baculovirus vector is sufficient disclosure to support that at the time of filing ***circular*** replication-deficient baculovirus vector as claimed was not used in methods for cloning using

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baculovirus at the time of filing. Dr. Possee sets forth in his Declaration filed 10/30/07 that at the time of filing the state of the art of methods using baculovirus in recombination and cloning methods required linearized DNA and not circular DNA. Specifically, the Declaration of Dr. Possee provides an overview of the methods of expression using Baculovirus known in the art (see BD BacPAK filed 10/30/07). The method of expression uses a linearized BD BacPAK6 Viral DNA and a transfer vector that are used to transfect an insect host. Plaques are purified and the phenotype confirmed. Following the purification, virus is used to infect insect cells to produce the protein. Applicants argue that in Campos et al based upon the art at the time of filing, the transfer vectors (rescue vectors) are demonstrated to be pBacHISgD:LH, which is based upon BacPAK vectors and hence complementary vector for recombination would be pBAK 8 and 9, which Clontech demonstrates is linearized. In example 4, Campos et al teach that the transfer vector and pBacHISgD:LH are co-transfected into insect cells, recombinant virus is plaque purified, the phenotype confirmed and subsequent infection undertaken for protein purification. Dr. Possee notes the portrayed method of example 4 confirms that the DNA was linear DNA due to the requirement for plaque purification, which step is not required of methods using circular DNA (see table 1 of the instant specification, page 4). The requirement for plaque purification and absence of specific disclosure in the art of *circular* vectors prior to the instant invention confirms that the method of Campos et al was not intended to advance the art by teaching use of circular DNA.

The amendment to claim 27 is in part to correct grammatical inconsistencies and in part (iv) to clarify the purpose of infecting a second cell.


It is noted that an artifact folder filed 10/21/05 within which was identified a Declaration. This Declaration was subsequently filed by applicants on 12/07/05 and considered. The contents of the folder have been scanned.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Maria B Marvich, PhD
Examiner
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